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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,884	03/21/2001	Russell John Mumper	50229-262	1135

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/812,884	MUMPER ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgment of Papers Received: Response filed 1/22/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-23, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al (USPN 5,658,575 hereafter referred to as '575). The claims are drawn to a method of making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest. The method further comprises heating the oil-in-water emulsion and then cooling it at room temperature.

'575 discloses a method form making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest abstract). The oil-in-water emulsion comprises hydrophilic surfactants such as polyoxyethylene sorbitan fatter acids (col. 3, lin. 42 – 60), and molecules of interest such as vitamins and pharmaceutically active agents (col. 4, lin. 56 – col. 5, lin. 30). The nanoparticles have an average mean particle size below 200 nm (col. 3, lin. 15 – 25). The particles are formed by mixing the surfactant with the molecule of interest, heating the oil-in-water emulsion to a temperature between 20 and 90 degrees Celsius and cooling the resultant at room temperature while stirring (col. 6, lin. 10 – col. 7, lin. 10). These disclosures among others render the claims anticipated.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 24 – 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al (USPN 5,658,575 hereafter referred to as '575). The claims are drawn to a method of making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest. The method further comprises heating the oil-in-water emulsion and then cooling it at room temperature.

As discussed above '575 discloses a method for making a nanoparticle comprising making an oil-in-water emulsion comprising a drug and a surfactant, heating the emulsion, cooling the resultant to achieve a nanoparticle with average size below 300 nm (abstract). The reference however lacks some of the specific concentrations recited in the claims.

Regarding claims 24, 26, 28 and 29 it is the position of the examiner that such limitations do not impart patentability on the claims, and in light of the prior art can be determined through routine experimentation. '575 discloses the essential elements of the invention. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

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Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various nanoparticle compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claim 25, it is the position of the examiner that the limitation does not impart patentability on the claim. It is the position of the examiner that in view of the prior art, a skilled artisan would be able to use the procedures disclosed in '575 to achieve a particle size below 100 nm. Though not enumerated in the particular reference a skilled artisan would be motivated to continue to reduce the particle size of the nanoparticle composition in order to increase the surface area and bioavailability of the resultant formulation.

With these things in mind a skilled artisan would have been motivated to follow the suggestions and teachings of the prior art in order to optimize the nanoparticle of '575. A skilled artisan would have been motivated to follow the teachings of '575 to modify and optimize the concentrations of the surfactant and molecule of interest. A skilled artisan would have been motivated to continue to reduce the particle size of the nanoparticle formulation in order to increase the surface area and increase the bioavailability of the formulation. It would have been obvious to a skilled artisan to modify the teachings and suggestions of the art with an expected result of a process for making an improved nanoparticle with improved bioavailability.

Response to Arguments

6. Applicant's arguments filed 1/22/04 have been fully considered but they are not persuasive. Applicant argues that:

- a. Ribier does not disclose a microemulsion as recited in the instant claims
- b. Ribier does not disclose nanoparticles as recited by the instant claimed invention
- c. Ribier does not disclose a cooling step as recited in the claimed invention
- d. Ribier cannot be used as prior art for recitations of specific concentrations since they are not expressly disclosed.

7. With regard to argument a., it is the position of the examiner that though the emulsion of Ribier is designated an emulsion, the instant claims leave open the possibility of creating an emulsion. Emulsions require only an oil, water, surfactant and energy. Microemulsion on the other hand require oil, water, surfactant and co-surfactant. The claims open claim language do not require the inclusion of a co-surfactant, and leave open to possibility of further energy steps such as homogenization in order to stabilize the preparation. Further the stability of the formulation is not recited by the claims, yet applicant posits this as a distinction between the formulation of the prior art and the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., stability) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In essence the method of claim 21 could produce an emulsion, since the language is open to the inclusion of homogenizing step and does not require a co-surfactant for its success.

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Regarding argument b., applicant merely requires a liquid nanoparticle matrix material, and this component is provided in Ribier. The reference discloses a liquid nanoparticle, which is recited in the claimed invention. A one solid phase nanoparticle is not claimed in the instant claims, and the limitation cannot be read into the claims. Again the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding argument c., it is the position of the examiner that Ribier in fact discloses a method for making nanoparticles where a composition is cooled, and nanoparticles are formed. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The nanoparticles of the instant claims are formed from mixing a surfactant, and a molecule of interest with water, heating and cooling. The essential components are identical. Applicant is invited to provide a functional distinction between the nanoparticles claimed and those of the prior art.

Regarding argument d., applicant is reminded that the general conditions of the claims are met. A nanoparticle composition is formed from a molecule of interest, water, and a surfactant. It is not patentable to recite optimized concentrations ranges, where the general

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conditions are met. By applicant's own admission, the process for making the nanoparticle of the invention is a known practice. The concentration of each component would be a mere reduction of practice to a skilled artisan. Applicant is invited to provide any unexpected results, establishing the criticality of the concentrations ranges recited in the claims. Barring a showing of unexpected result to these particular ranges and concentrations, the claims will remain obviated by the prior art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

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